MAY 25 2012

6 510(k) Summary

510(k) Summary –Synthes ACIS	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin, Ph.D., P.E. Senior Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	January 27, 2012
Trade Name(s):	Synthes ACIS
Classification:	21 CFR 888.3080 – Intervertebral fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code ODP (Intervertebral Fusion Device with Bone Graft, Cervical)
Predicates:	Synthes Zero-P device (K072981) NuVasive CoRoent System (K081611) BAK Cervical Interbody Fusion System (P980048) Medtronic Cornerstone PSR (K100214) Medtronic Prevail (K073285) Globus PATRIOT™ Spacers (Colonial™ ACDF) (K072991)
Device Description(s):	The Synthes ACIS is a radiolucent cervical intervertebral body fusion device. The Synthes ACIS is fabricated from Invibio® PEEK-Optima® LT-1 (ASTM F2026-10) with two anterior and one posterior titanium alloy (Ti-6Al-4V ELI; TAV; ASTM F136-2a) radiopaque markers. The markers allow intra-operative radiographic assessment of the position of the implant. The Synthes ACIS is available in a range of heights, in three different sagittal profiles. Pyramidal teeth that assist in stabilization of the construct are located on the inferior and superior surfaces of the spacers. The open architecture of the device allows it to be packed with autogenous bone graft material, *i.e.*, autograft.
Intended Use/ Indications for Use:	The Synthes ACIS is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the Synthes ACIS should be packed with autogenous bone graft and implanted via an anterior approach. The Synthes ACIS is intended to be used with supplemental fixation.
Comparison of	Synthes ACIS is substantially equivalent to the predicates in design,

510(k) Summary –Synthes ACIS	
the device to predicate device(s):	function, performance, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Synthes conducted the following bench testing (as recommended within FDA Guidance and in accordance with ASTM F2077-03 and ASTM F2267-04): Static Axial Compression; Dynamic Axial Compression; Static Compression Shear; Dynamic Compression Shear; Static Torsion; Dynamic Torsion; and Subsidence. The conclusions drawn from testing demonstrate that the Synthes ACIS device is substantially equivalent in performance to predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

510(k) Summary –Synthes Vertebral Spacer CR	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin, Ph.D., P.E. Senior Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	January 27, 2012
Trade Name(s):	Synthes Vertebral Spacer CR
Classification:	21 CFR 888.3080 – Intervertebral fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code ODP (Intervertebral Fusion Device with Bone Graft, Cervical)
Predicates:	Synthes Zero-P device (K072981); NuVasive CoRoent System (K081611); BAK Cervical Interbody Fusion System (P980048); Medtronic Cornerstone PSR (K100214); Medtronic Prevail (K073285); Globus PATRIOT™ Spacers (Colonial™ ACDF) (K072991)
Device Description(s):	The Synthes Vertebral Spacer CR is a radiolucent cervical intervertebral body fusion device. The Vertebral Spacer CR is fabricated from Invibio® PEEK-Optima® LT-1 (ASTM F2026-10) with two anterior and one posterior titanium alloy (Titanium-6Aluminum-7Niobium ASTM F1295-05) radiopaque markers. The markers allow intra-operative radiographic assessment of the position of the implant. The Synthes Vertebral Spacer CR is available in a range of heights, and is available in three different sagittal profiles. Pyramidal teeth that assist in stabilization of the construct are located on the inferior and superior surfaces of the spacers. The open architecture of the device allows it to be packed with autogenous bone graft material, *i.e.*, autograft.
Intended Use/ Indications for Use:	The Synthes Vertebral Spacer CR is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the Synthes Vertebral Spacer CR should be packed with autogenous bone graft and implanted via an anterior approach. The Synthes Vertebral Spacer CR is intended to be used with supplemental fixation.
Comparison of the device to predicate	Synthes Vertebral Spacer CR is substantially equivalent to the predicates in design, function, performance, material, and intended use.

510(k) Summary –Synthes Vertebral Spacer CR	
device(s):	
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Synthes conducted the following bench testing (as recommended within FDA Guidance and in accordance with ASTM F2077-03 and ASTM F2267-04): Static Axial Compression; Dynamic Axial Compression; Static Compression Shear; Dynamic Compression Shear; Static Torsion; Dynamic Torsion; and Subsidence. The conclusions drawn from testing demonstrate that the Synthes Vertebral Spacer CR device is substantially equivalent in performance to predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Spine
% Heather Guerin, Ph.D., P.E.
Senior Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

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Re: K120275
Trade/Device Name: ACIS Spacer and Vertebral Spacer CR
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 24, 2012
Received: April 26, 2012

Dear Dr. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

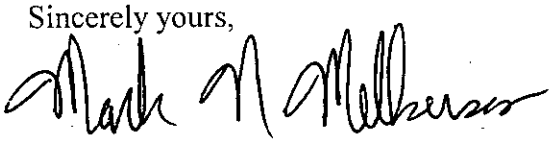
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(k) Number: K 120275
(if known)

Device Name: Synthes ACIS

Indications for Use: The Synthes ACIS is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer of the Synthes ACIS should be packed with autogenous bone graft and implanted via an anterior approach. The Synthes ACIS is intended to be used with supplemental fixation.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120275

510(k) Number: K 120275
(if known)

Device Name: Synthes Vertebral Spacer CR

Indications for Use: The Synthes Vertebral Spacer CR is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the Synthes Vertebral Spacer CR should be packed with autogenous bone graft and implanted via an anterior approach. The Synthes Vertebral Spacer CR is intended to be used with supplemental fixation.

Prescription Use X	AND / OR	Over-the-Counter Use
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120275